

FORM PTO-1390 (Modified)  
(REV 11-98)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

## TRANSMITTAL LETTER TO THE UNITED STATES

(H) 97OM1412USP

DESIGNATED/ELECTED OFFICE (DO/EO/US)

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.5)

CONCERNING A FILING UNDER 35 U.S.C. 371

09/529742

INTERNATIONAL APPLICATION NO.

INTERNATIONAL FILING DATE

PRIORITY DATE CLAIMED

PCT/IB97/01634

17/10/97

TITLE OF INVENTION

Stomatic Composition

APPLICANT(S) FOR DO/EO/US

Rudin et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
  - a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ has been transmitted by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ A copy of the International Search Report (PCT/ISA/210).
8. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ have been transmitted by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
9. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
10. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). *UNEXERCISED*
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409)
12. ☒ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

## Items 13 to 20 below concern document(s) or information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☒ Certificate of Mailing by Express Mail
20. ☒ Other items or information:

General Authorization to Charge Fees

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.5) <b>09/529742</b>	INTERNATIONAL APPLICATION NO. <b>PCT/IB97/01634</b>	ATTORNEY'S DOCKET NUMBER <b>(H) 97OM1412USP</b>
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21. The following fees are submitted:

**BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :**

- ☐ Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO . . . . . **\$970.00**
- ☒ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO . . . . . **\$840.00**
- ☐ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO . . . . . **\$690.00**
- ☐ International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4) . . . . . **\$670.00**
- ☐ International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) . . . . . **\$96.00**

**ENTER APPROPRIATE BASIC FEE AMOUNT =****\$840.00**

Surcharge of **\$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).

**\$0.00**

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE
Total claims	10 - 20 =	0	x \$18.00
Independent claims	2 - 3 =	0	x \$78.00

**\$0.00****\$0.00**Multiple Dependent Claims (check if applicable). ☐**\$0.00****TOTAL OF ABOVE CALCULATIONS =****\$840.00**

Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28) (check if applicable). ☐

**\$0.00****SUBTOTAL =****\$840.00**

Processing fee of **\$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (f)).

**\$0.00****TOTAL NATIONAL FEE =****\$840.00**

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable). ☐

**\$0.00****TOTAL FEES ENCLOSED =****\$840.00**

Amount to be: refunded	\$
charged	\$

☒ A check in the amount of **\$840.00** to cover the above fees is enclosed

☐ Please charge my Deposit Account No. \_\_\_\_\_ in the amount of \_\_\_\_\_ to cover the above fees.  
A duplicate copy of this sheet is enclosed.

☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. **11-0665** A duplicate copy of this sheet is enclosed.

**NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.**

SEND ALL CORRESPONDENCE TO:

**M. Robert Kestenbaum**  
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Albuquerque, NM USA 87111  
Phone (505) 323-0771  
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*M. Robert Kestenbaum*

SIGNATURE

**M. Robert Kestenbaum**

NAME

**20,430**

REGISTRATION NUMBER

**April 17, 2000**

DATE

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) AND 1.27 (c)) - SMALL BUSINESS CONCERN			Docket No. (H)97OM1412USP
Serial No. PCT/IB97/01634	Filing Date October 17, 1997	Patent No.	Issue Date
Applicant/ Rudin et al. Patentee.			
Invention: Stomatic Composition			
<p>I hereby declare that I am:</p> <p><input type="checkbox"/> the owner of the small business concern identified below:</p> <p><input checked="" type="checkbox"/> an official of the small business concern empowered to act on behalf of the concern identified below:</p> <p>NAME OF CONCERN: <u>Aktsionernoe Obschestvo Zakrytogo Tipa "Ostim"</u></p> <p>ADDRESS OF CONCERN: <u>per. Sechenovskiy, 6-3, Moscow, 119034, Russia</u></p> <p>I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 37 CFR 1.21.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.</p> <p>I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the above identified invention described in:</p> <p><input type="checkbox"/> the specification filed herewith with title as listed above.</p> <p><input checked="" type="checkbox"/> the application identified above.</p> <p><input type="checkbox"/> the patent identified above.</p> <p>If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed on the next page and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 CFR 1.9(c) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).</p>			

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re: New US Patent Application corresponding to  
International Application PCT/IB97/01634  
Filed October 17, 1997  
Applicant Rudin et al.  
Attorney Docket (H) 97OM1412USP

Assistant Commissioner for Patents  
Washington, DC 20231

Preliminary Amendment

Dear Sir or Madam:

Please amend the above-identified application as follows:

In the Claims:

Claim 5, lines 1 and 2, after "according to" cancel "one of claims 1 to 4" and  
insert -- claim 1--.

Claim 6, line 1, after "according to" cancel "one of claims 1 to 5" and insert --  
claim 1--.

Claim 7, line 1, after according to" cancel "one of claims 1 to 6" and insert --claim  
1--.

Claim 8, line 1, after according to" cancel "one of claims 1 to 7" and insert --claim  
1--.

Claim 9, line 1, after according to" cancel "one of claims 1 to 8" and insert --claim  
1--.

Claim 10, line 1, after according to" cancel "one of claims 1 to 9" and insert --  
claim 1--.

Remarks

This Preliminary Amendment removes multiple dependencies from the claims.

Please calculate the Filing Fee according to this Preliminary Amendment.

Respectfully submitted,



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Rec'd PCT/PTO 17 APR 2000

09/529742

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Ostim

STOMATIC COMPOSITION

Description

Field of the Invention

This invention relates to the field of medicine, and in particular to the field of stomatology and may be used for preventive treatment and curing of caries, parodontitis and paradentosis.

Prior art

For these above-captioned purposes, stomatic compositions comprising hydroxyapatite (HA) have found an extensive application in the stomatologic practice.

There are certain compositions having a favourable effect including synthetic HA containing 92 to 97%  $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ , 3 to 6%  $\text{H}_2\text{O}$  and 0,3%  $\text{CaCO}_3$  with an average particle size of 1 to 15 nm.

Such a stomatic composition, for instance, according to Patent EP 0344832 cl. A61K 7/16, comprises save the stated HA, water-soluble casein material or sodium trimetaphosphate, as an anti-caries agent and also other well known ingredients which depend upon the forms of the product manufactured, such as various humectants, binding thickeners, surfactants, flavouring agents.

The known stomatic composition (EP 0342726 03442745 cl. A61K 7/18, publ.23.11.89) supplementary includes a fluorine-containing compound in the form of NaF or sodium monophosphosphate as an anti-caries agent.

The amount of HA present in the stomatic composition is in the range of 1 to 50%, usually 2 to 20% by weight of the stomatic composition. The stomatic composition comprises some other ingredients: humectants, thickeners, surfactants

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and flavouring agents commonly known to those skilled in the art in all formulations of such products.

However, the stomatic compositions stated possess a relatively poor anti-carries effect and is not useful in the preventive medicine and in the treatment of inflammatory-destructive diseases of parodontium tissues.

#### Disclosure of the invention

It is an object of the present invention to create a stomatic composition comprising compounds capable to cure microdefects of the basic substance of the dental enamel to combat caries developing (e.g. to provide an anti-carries activity) and to prevent the spread of such inflammable-destructive diseases of parodontium tissues as paradenitis and parodontosis, and also compounds capable to stimulate reparative osteogenesis processes and possessing high bioactivity and specific pharmacological activity.

It is a further object of the invention to create a stomatic composition being identic to the basic substance of the dental enamel in its substance contents and crystalline parameters, as the acid formed in the materials covering dental surfaces causes destruction of mineral hydroxyapatyte out of which enamel is composed and has a result due to which calcium ion loss occurs.

The task surprisingly has been solved in a composition as defined in claim 1.

A preferred composition having a more pronounced effect in view of the improvements obtained according to the invention comprises particles of hydroxyapatite with an average particle size in length (l), width(d) and thickness(h) of about  $l = 0,06 \mu\text{m} \pm 50 \%$ ,  $d = 0,015 \mu\text{m} \pm 50 \%$  and  $h = 0,005 \mu\text{m} \pm 50 \%$ .

A most preferred composition having a surprisingly superior effect in view of the improvements obtained according to the invention comprises particles of hydroxyapatite with an average particle size in length (l),

width(d) and thickness(h) of l about 0,06  $\mu\text{m}$ , d about 0,015  $\mu\text{m}$ , h about 0,005  $\mu\text{m}$ .

Being introduced into the composition, HA possesses osteo-reparative properties and contains preferably about 100%  $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ .

The specific surface of HA used in the composite advantageously is 100 to 150  $\text{m}^2/\text{g}$ .

The amount of HA present in the oral composition of the present invention is in the range of 0,1% to 50%, preferably from 0,1% to 25%, and most preferably from about 0,2% to 20% by weight of the oral composition.

The composition reacts to a change in the biochemical environment, for instance a rapid dissolvment of ultra finely divided HA occurs when the pH is decreasing, that provides an active utilization of Ca and  $\text{PO}_4$  - ions in the osteogenesis process: the size and configuration of the inventive crystals are adapted to the maximum to the dental enamel structure, which is mostly composed of HA, that suggests its use in the osteo-reparative process as a building material.

The ultra finely divided HA possesses a high adhesive-sorption activity to the dental enamel and to microdefects on its surface, that favour the preventive measures preventing the spread of caries disease and also possesses a high sorption activity in respect to proteins and aminoacids of parадentium tissues, that stimulates an active preventive treatment of the inflammable-destructive diseases such as paradenitis and parадentosis.

Moreover, the stomatic composition of the present invention will contain other conventional ingredients in addition to HA possessing osteo-reparative properties, whose introduction into the composition depends on the form of the product. For instance, in the case of an oral product in the form of dentifrice paste, cream or gel, the product will comprise a liquid phase containing humectants and binding thickeners which act to maintain the particulate solid

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abrasive and HA crystals in the form of stable suspension in the liquid phase.

Surfactants and flavouring agents are also usual ingredients for various inventive embodiments of oral compositions.

The humectants usually used are glycerol or sorbitol. However, other humectants may be used according to the invention including polyethyleneglycol, propyleneglycol, lactitol and hydrogenated corn syrup. The amount of humctant will generally range from about 0% to 85% by weight of product. The remainder of the liquid phase will consist substantially of water. The liquid phase can be water or a non-aqueous composition.

As binding agents and thickeners, various substances can be used such as sodium carboxymethylcellulose, sodium hydroxyethylcellulose and xanthan gum. Natural gum bindings can be included such as gum tragacanth, gum karaya of Irish moss, etc. Any mixture of binding agents and thickeners can be also used. The amount of bindings and thickeners usually included into the oral composition is in the range of 0% to 10% by weight of the oral composition.

Moreover, any materials as widely disclosed in the literature generally also might be used for the invention as surfactants, i.e. surfactants like sodium lauryl sulphate, dodecylbenzene sulphonate and sodium lauryl sarcosinate. Other anionic surfactants also can be used as well as cationic and amphoteric and non-ionic surfactants. Surfactants are generally present in the composition in the amount of 0% to 5% by weight of the oral composition.

Flavours that are generally used in the oral compositions are those based on oils of spearmint and peppermint and might be used for the invention. Examples of other flavouring materials used are menthol, clove, wintergreen, eucalyptus and aniseed. A preferable amount of flavours is from 0% to 5% by weight in respect to the oral composition.

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As abrasive materials, silica dioxide of various modifications, aluminium oxide, calcium carbonate, dicalcium phosphate anhydrite, dicalcium phosphate dihydrate, sodium metaphosphate insoluble in water, and thereof mixtures may be used. The amount of abrasive materials ranges from 0.0% to 25%. The oral composition may include a wide variety of optional ingredients. These include antimicrobial and anti-plaque agents for example chlorhexidine or 2,4,4-trichloro-2hydroxy-diphenyl ether, or zink compounds (see EPA-161898) anti-tartar ingredients such as condensed phosphates, e.g. alkali et al pyrophosphates, hexametaphosphates or polyphosphates (see US-A-4 515772 and US-A-4 627977) or zink citrates (see US-A-4 100269), sweetening agents such as saccharin. Preservatives such as formalin, sodium benzoate. colouring agents (for instance titanium dioxide) or pH-controlling agents, such as acid base or buffer agents the oral composition may also include agents enhancing the gingivitis system of the mouth cavity and representing extracts of various natural plants such as urtica, millefolium, chamomilla hypericum, salvia, etc. in the aqueous or aqueous-alcoholic forms.

The stomatic composition depending on its form (dentifrice paste, cream or gel) is maintained in contact with the tissue of the oral cavity from 15 sec to 12 hours.

The following examples of dentifrice pastes and gel comprising synthetic ultra finely divided HA possessing osteo-reparative properties as described above illustrate the invention. Percentages and parts of the components are by weight.

Belowstanding preferred embodiments of the invention are shown in its composition.

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Examples N1 and 2.

Toothpaste prepared from the following ingredients.

Ingredients, %		
Example	1	2
Ultra finely divided		
Hydroxyapatite	0,2	2,0
Silica aerogel	22,0	15,0
Sodium carboxymethylcellulose	1,0	1,0
Glycerol distilled	20,0	20,0
Sorbitol	20,0	17,0
Titanium dioxide	0,6	0,5
Sodium benzoate	0,4	0,6
Aqueous-alcohol extract of chamomilla	1,0	0,8
Aqueous-alcohol extract of hypericum	1,0	0,8
Sodium saccharin	0,1	0,06
Flavour	1,0	1,3
Sodium lauryl sulphate	1,5	1,5
Water	to 100,0	to 100,0

Examples N 3 to 7

Toothpaste prepared from the following ingredients.

Ingredients, %					
Example	3	4	5	6	7
Ultra finely divided					
hydroxyapatite	2,5	2,5	2,5	2,5	2,5
Silica aerogel	17,0	17,0	17,0	17,0	17,0
Sodium					
hydroxyethylcellulose	1,6	-	-	1,6	-
Sodium					
carboxymethylcellulose	-	1,1	1,1	-	0,9
Sorbitol	20,0	20,0	16,0	20,0	20,0
Glycerol distilled	20,0	20,0	20,0	20,0	20,0
Polyethyleneglycol	-	-	5,0	-	-
Sodium lauryl sulphate	1,5	1,5	1,5	1,5	1,5
Tetrasodium pyrophosphate	-	1,5	-	-	-
Tetrapotassium					
pyrophosphate	-	-	-	2,5	-
Sodium trimetaphosphate	-	-	2,0	-	-
Zinc citrate trihydrate	-	-	-	-	0,5
Titanium dioxide	0,6	0,6	0,6	0,6	0,6
Sodium benzoate	0,5	0,5	0,6	-	-
Formalin	-	-	-	0,05	0,05
Aqueous-alcohol extract					
of salvia	0,5	0,5	-	-	-
Aqueous-alcohol extract					
of millefolium	0,9	0,9	0,5	0,5	-
Aqueous-alcohol extract					
of chamomilla	-	-	1,0	0,7	-
Triclosan	-	-	0,2	-	0,2
Sodium saccharin	0,06	0,06	0,06	0,06	0,06

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Flavour	1,0	1,0	1,0	1,0	1,0
Water	in all example to 100,0				

Examples N8 and 9

Gel preventing paradentitis.

## Ingredients, %

Example	8	9
Ultra finely divided		
hydroxyapatite	5,0	4,0
Sodium hydroxyethylcellulose	2,0	2,5
Silica aero	5,0	-
Glycerol distilled	10,0	-
Sorbitol	25,0	45,0
Sodium benzoate	0,5	-
Triclosan	-	0,3
Flavour	0,2	0,15
Sodium lauryl sulphate	0,2	0,15
Sodium saccharin	0,07	0,07
Water	to 100,00	to 100,00

Industrial application

The stomatic composition can be used to cure microdefects of the basic substance of the dental enamel, e.g. to prevent the spread of caries, and is also useful for

preventive measures avoiding the spread of inflammable-destructive diseases of parodontium tissues, such as parodontitis and parodontosis.

The stomatic composition can be used in the form of tooth pastes, tooth creams and gels. Moreover, the composition can be included as a component in chewing gum, pastilles, tooth elixir and formulations to rinse mouth.

The stomatic composition according to the invention is capable to stimulate reparative osteogenesis processes and possessing a high bioactivity and specific pharmacological activity. Moreover, this composition is useful for combatting dental caries and to prevent the spread of such inflammable-destructive diseases of parodontium tissues as parodontitis and parodontosis, on the basis of hydroxyapatite also optionally comprising abrasive materials, humectants, thickeners, surfactants, flavouring agents, and a number of optional ingredients.

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Claims:

1. A ~~stomatic~~-composition for stomatic applications characterised in that it comprises particles of hydroxyapatite with an average particle size in length (l), width (d) and thickness (h) of: l from ~~about~~ 0,2 mm to ~~about~~ 0,01 mm, d from ~~about~~ 0,1 mm to ~~about~~ 0,001, and h from ~~about~~ 0.1 mm to ~~about~~ 0,0001 mm.

2. The ~~stomatic~~-composition according to claim 1 characterised in that it comprises particles of hydroxyapatite with an average particle size in length (l), width (d) and thickness (h) of ~~about~~ l = 0,06 mm +/- 50 %, d = 0,015 mm +/- 50 % and h = 0,005 mm +/- 50 %.

3. The ~~stomatic~~-composition according to claim 1 characterised in that it comprises particles of hydroxyapatite with an average particle size in length (l), width (d) and thickness (h) of ~~about~~ l = 0,06 mm, d = 0,015 mm, h = 0,005 mm.

4. A ~~stomatic~~-composition for stomatic applications characterised in that it comprises particles of hydroxyapatite having a specific surface of hydroxyapatite from ~~about~~ 100 m<sup>2</sup>/g to ~~about~~ 150 m<sup>2</sup>/g.

5. The ~~stomatic~~-composition according to one of claims 1 to 4 characterized in that it comprises said hydroxyapatite particles ultra finely divided.

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6. The composition according to one of claims 1 to 5 characterised in that the ultra finely divided hydroxyapatite particles are present in the composition in an amount of 0,1% to 50% by weight.

7. The composition according to one of claims 1 to 6 characterised in that the ultra finely, divided hydroxyapatite is a synthetic hydroxyapatite which contains 99,9% of  $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$  by weight.

8. The composition according to one of claims 1 to 7 further characterised by at least one substance of the group consisting of

- humectants in a range from ~~about~~ 0% to 85% by weight,
- bindings and thickeners a range of 0% to 10% by weight,
- abrasive materials in a range from 0.0% to 25%,
- Surfactants in a range from 0% to 5% by weight,
- Flavours in a range from 0% to 5% by weight.

9. The composition according to one of claims 1 to 8 further characterised by agents enhancing the gingivitis system of the mouth cavity and comprising extracts of natural plants including at least one of the group consisting of urtica, millefolium, chamomilla hypericum, salvia, ~~etc~~ in the aqueous an in the aqueous-alcoholic form.

10. The composition according to one of claims 1 to 9 further characterised by antimicrobial and anti-plaque agents.

AMENDED SHEET



Docket No.  
(H)9701412USP

# Declaration and Power of Attorney For Patent Application

## English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

**Stomatic Composition**

the specification of which

(check one)

☐ is attached hereto.

☒ was filed on October 17, 1997 as United States Application No. or PCT International Application Number PCT/IB97/01634 and was amended on \_\_\_\_\_

(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)			Priority Not Claimed
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/>
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/>
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/>

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

\_\_\_\_\_  
(Application Serial No.)

\_\_\_\_\_  
(Filing Date)

\_\_\_\_\_  
(Application Serial No.)

\_\_\_\_\_  
(Filing Date)

\_\_\_\_\_  
(Application Serial No.)

\_\_\_\_\_  
(Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C. F. R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

**PCT/IB97/01634**

**10/17/97**

**Pending**

\_\_\_\_\_  
(Application Serial No.)

\_\_\_\_\_  
(Filing Date)

\_\_\_\_\_  
(Status)  
(patented, pending, abandoned)

\_\_\_\_\_  
(Application Serial No.)

\_\_\_\_\_  
(Filing Date)

\_\_\_\_\_  
(Status)  
(patented, pending, abandoned)

\_\_\_\_\_  
(Application Serial No.)

\_\_\_\_\_  
(Filing Date)

\_\_\_\_\_  
(Status)  
(patented, pending, abandoned)

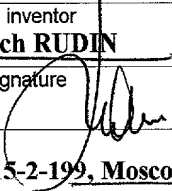
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

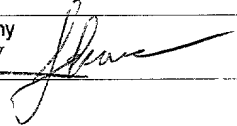
POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(list name and registration number)*

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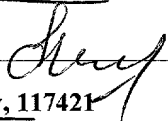
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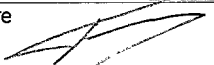
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Ninth inventor's signature	Date
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